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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/694,457

10/27/2003

Josef E. Gorek

G-110

2516

7590

07/02/2004

Joseph P. Errico  
150 Douglas Road  
Far Hills, NJ 07901

EXAMINER

RAMANA, ANURADHA

ART UNIT

PAPER NUMBER

3732

DATE MAILED: 07/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/694,457

Applicant(s)

GOREK, JOSEF E.

Examiner

Anu Ramana

Art Unit

3732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 14-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10/27/03 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

Art Unit: 3732

**DETAILED ACTION**

The Attorney of Record, Timothy Bortree, canceled claims 1-13, during a phone conversation on June 25, 2004 since the instant application is a divisional of parent application 10/103,079 (now US 6,638,281). In the parent application, claims 1-13 were elected for prosecution. Accordingly, this Office Action addresses claims 14-20 now pending in the instant application.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gispert (US 2,666,430 or '430 herein) in view of Mac-Thiong et al. (US 6,342,056 or '056 herein).

'430 discloses a guiding device for use in orthopedic surgery to drive a drill into a bone, the device including a guide shaft 11, mounting means 9b and manual longitudinal and transverse angular deviation adjusting means 8a, 8b and 9d for adjusting the angular deviation of guide shaft 11 with respect to a reference point, so that the drill penetrates a bone at a predetermined point (Fig. 1, col. 1, lines 5-11, col. 2, lines 12-55, col. 3, lines 1-75 and col. 4, lines 1-18).

'430 discloses the claimed invention except for a leveling device. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized a bubble type level (as evidenced by US 3,052,036) instead of the manual adjusting means 8a and 9d, since it has been held that broadly providing a mechanical or automatic means to replace manual activity which has accomplished the same result involves only routine skill in the art. *In re Venner*, 120 USPQ 192.

'430 does not specifically disclose drilling a pedicle screw tap or "pilot" hole.

Art Unit: 3732

'056 discloses a common technique for inserting a pedicle screw including: preparation of a pilot hole through the pedicle by first selecting the insertion angle with a CT scan and then drilling the hole (col. 1, lines 21-40 and Fig. 2).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized the '430 device for a common surgical procedure, as taught by '056, for pedicle screw insertion.

The method steps of determining a trajectory angle or "angle of insertion", adjusting the guide shaft to match the trajectory angle, positioning a distal end of a drill bit in a vicinity of a base of a superior articular process and a base of a transverse process of a pedicle and rotating the drill bit into the pedicle are rendered obvious by the above discussion.

Claim 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gispert (US 2,666,430 or '430 herein) in view of Mac-Thiong et al. (US 6,342,056 or '056 herein) and Foley et al. (US 6,226,548).

Gispert does not disclose the use of a spinal clamp as reference point.

Foley et al. teach the use of fiducial markers or reference points, such as rods and clamps, to indicate the position of spinal elements such as vertebrae during imaging procedures such as CT, MRI or other methods for spinal surgical procedures (col. 2, lines 26-67, col. 3, lines 1-8 and lines 29-50).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized a clamp, as taught by Foley et al., during an imaging procedure in the method of the combination of Gispert and Mac-Thiong et al., as a reference point to fix the position of a vertebra and to make all measurements therefrom.

### *Conclusion*


The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.


Art Unit: 3732

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (703) 306-4035. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached at (703) 308-2582. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AR   
June 26, 2004

  
**EDUARDO C. ROBERT**  
**PRIMARY EXAMINER**